OLR Bill Analysis

HB 5347

AN ACT CONCERNING PRESCRIPTION DRUG LABELS.

SUMMARY:

This bill requires pharmacists to label generic prescription drugs with both the generic name of the drug and the brand name, in the form: "_____ Generic for _____." Currently, the brand name is not required on generic drug labels.

EFFECTIVE DATE: January 1, 2014

BACKGROUND

Related Law - FDA Regulation of Prescription Drug Labeling

The U.S. Food and Drug Administration (FDA) regulates prescription drug labeling and preempts state regulation in some areas. The U.S. Supreme Court ruled that the FDA did not have exclusive jurisdiction over prescription drug labeling in a case that allowed a lawsuit for damages to proceed against a brand name drug manufacturer based on a state law claim of inadequate warning labels (*Wyeth v. Levine*, 129 S.Ct. 1187 (2009)). But, the Court found that a similar state law claim against a generic manufacturer conflicted with and was preempted by federal regulations that required generic drug labels to be identical to FDA-approved labels (*Pliva, Inc. v. Mensing*, 131 S.Ct. 2567 (2011)). The preempted suit could have resulted in requiring a generic drug manufacturer to update labeling to reflect newly discovered side effects, something the manufacturer could not legally do alone, without the FDA acting.

COMMITTEE ACTION

General Law Committee

Joint Favorable
Yea 15 Nay 3 (03/12/2013)